



4,374,858
DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 27 1995

Food and Drug Administration
Rockville MD 20857

Francis J. Tinney
Assistant Secretary
Patent Department
Warner-Lambert Company
2800 Plymouth Road
Ann Arbor, MI 48105

Re: Neutrexin™
Docket No. 94E-0099/ PRC1

Dear Mr. Tinney:

This is in response to your September 1, 1995 request for redetermination of the beginning and end of the testing phase and the beginning of the approval phase for Neutrexin™ (trimetrexate glucuronate), as stated in the August 30, 1994 Federal Register Notice (59 Fed. Reg. 44,737), submitted on behalf of Warner-Lambert Company ("Applicant"). While your request for redetermination was not filed timely, FDA records reveal an error in the NDA receipt date as published.

When the Federal Register was published on August 30, 1994, all interested parties, including the Applicant, were provided 60 days, specifically until October 31, 1994, to comment and ask for a redetermination of the regulatory review period dates. According to 21 CFR § 60.26, the regulatory review period is final after a 180-day period following the publication of the original Federal Register notice has passed or after a request for revision of the regulatory review period has been resolved. On March 22, 1995 FDA notified the Patent and Trademark Office that the regulatory review period was final because 180-day period had passed and there were no pending requests for revision of the regulatory review period. Your request for redetermination dated September 1, 1995, was received by FDA on September 5, 1995, making your request untimely.

However, because your petition for reconsideration states that an FDA official, Ms. Lisa Hubbard (the Consumer Safety Officer in the Antiviral Division who is currently responsible for Neutrexin™), indicated that the original regulatory review period was in error, your claims will be addressed to determine whether your claims are substantiated by official FDA records.

First, the petition claims that the IND became effective on September 2, 1987, the date the Applicant maintains that another FDA official, Mr. James Bona, orally notified the Applicant that the clinical hold on IND 29,796 (Neutrexin) had been lifted, not the date of the letter, October 21, 1987, that notified the Applicant that the clinical hold had been lifted. While the Applicant does have a company memorandum that documents such a conversation, there is no FDA record that describes this alleged conversation between Mr. Bona and the applicant, and

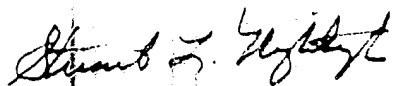
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this conversation is not referenced in any way in the official document of record, the letter dated October 21, 1987. Therefore, according to FDA records, the appropriate date for the beginning of the testing phase is October 21, 1987.

Secondly, the Applicant claimed that the date the NDA was initially submitted should be February 1, 1993, the date the NDA was received by FDA, not February 4, 1993, the date FDA sent the Applicant an acknowledgment letter of the NDA's receipt. Applicant is correct regarding this date. Upon review, FDA records confirm that the NDA was submitted on February 1, 1993, and it was officially received by the Agency on February 1, 1993. Therefore, February 1, 1993 should have been listed as the appropriate date for the NDA initially submitted date.

For these reasons, your request for redetermination has been affirmed in part and denied in part. A correction of the NDA initially submitted date will be published in the Federal Register, and a clarification of the discrepancy between Applicant's and FDA's records for the date when the clinical hold was lifted on its initial IND will also be made in the Federal Register.

Sincerely yours,



Stuart L. Nightingale, M.D.
Associate Commissioner for
Health Affairs

Attachment

cc: Stephen G. Kunin
Deputy Assistant Commissioner for
Patent Policy and Projects
U.S. Patent and Trademark Office
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, D.C. 20231